

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: February 8, 2000

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Project Management in the Office of Generic Drugs

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

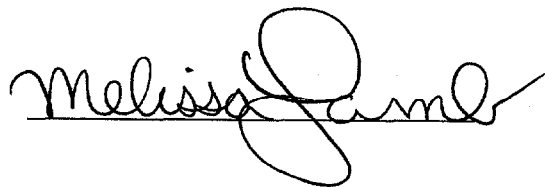
Title of Presentation: Project Management in the Office of
Generic Drugs

Presented for: 1999 Fall Technical Workshop

Date Presented: 10/18/99

Presented by: Pat Beers Block

Number of Pages: 19



Attachment

905-0308
FEB 11 2000 11:00 AM

905-0308

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Project Management in the Office of Generic Drugs

**Pat Beers Block, Chief
Review Support Branch
October 18, 1999**

OGD Project Management: Overview

- **History of Project Management**
- **Objectives**
- **Staff**
- **Program Initiatives**
- **Items to Consider**

OGD Project Management: History

- **CSOs/Project Managers introduced in early 1990's**
- **Large volume of work mandated additional staffing**
- **PMs assigned to Chemistry teams; expanded to include Bioequivalence PMs and Microbiology PM**
- **Chemistry PM = ANDA PM**
 - **responsible for overall coordination of ANDA review**

OGD Project Management: Objectives

- PMs focus on process and coordination of reviews**
- PMs help assure consistency and conformance with OGD policies and procedures**
- Facilitate resolution**

OGD Project Management: Tools to Help Meet Objectives

- **Master Queue**

- **Establishment Evaluation System**

OGD Project Management Staff

Team	Project Manager	Therapeutic Categories
Chemistry 1	Bonnie McNeal	Antihypertensive Angiotension Diuretics Radioactive/paques NonSteroidal AntiInflammatory
Chemistry 2	Michelle Dillahunt	Estrogens Gonadotropins Cytotoxic Antineoplastic Bronchodialator(MDI) Surgical-Dental/LVPs

OGD Project Management Staff

Team	Project Manager	Therapeutic Categories
Chemistry 3	Joe Buccine	AntiAnxiety Sedatives Dermatologics Otics/Ophthalmics Antifungal/Anti-infectives
Chemistry 4	Ruby Yu	Antipsychotics Corticosteroids Antihistamine Muscle Relaxant Contraceptives Anabolic Steroids Vitamins

OGD Project Management Staff

Team	Project Manager	Therapeutic Categories
Chemistry 6	Mark Anderson	Antibacterial Antifungal* Antineoplastic* Immuno-suppressants * Fermentation Derived
Chemistry 7	Kassandra Sherrod	Anti-Ulcer Anticonvulsants Antimotility Anticholinergics Anorexics

OGD Project Management Staff

Team	Project Manager	Therapeutic Categories
Chemistry 8	Timothy Ames	Beta-blockers Ca-Channel Blockers Antiarrhythmics Antidepressants Drug Abuse Treatment
Chemistry 9	Jeen Min	Antiviral Analgesics Anesthetics Narcotic Agonists Anticoagulants

OGD Project Management Staff

Team	Project Manager	Therapeutic Categories
Microbiology	Joe Buccine	All therapeutic categories requiring sterility assurance review

OGD Project Management: Initiatives

●Major/Minor/FAX Program

- Decrease administrative processing time**
- Prioritize amendments**
- August 1999 revision**

OGD Project Management: Initiatives

●DMF Faxing Program

- Streamlining initiative started in February, 1999**
- Reduces time between reviews and when deficiencies are sent to DMF holder**
- Comments faxed to DMF holder at the same time notice faxed to applicant that DMF deficient**

OGD Project Management: Initiatives

- **Automated tracking of 30 Day CBEs**
 - Report identifies CBEs requiring GRANT/DENY evaluation
 - Developed in anticipation of FDAMA requirements
- **Post Approval Commitment Computer Program**
 - Tracks status of post approval commitments
 - e.g.. M.V. samples; dissolution data

OGD Project Management: Initiatives

● Global Submission Program

- Started in 1994**
- Encourage firms to submit “global” supplement submission when:**
 - identical change affects 5 or more ANDAs with no specific data to be reviewed**
- Adds efficiency to review process**
 - one review affects all ANDAs included in global submission**
- Notify Global Coordinator in advance of submitting: Kassandra Sherrod**

OGD Project Management: Initiatives

● Managing Pending Approvals

- Weekly meetings attended by:**
 - Pat Beers Block, Chair**
 - Office Director/Deputy Director**
 - All Division Directors and Team Leaders**
 - Project Managers**
 - OGD Special Assist. For Legal Issues**
 - Office of Compliance representative**
- Discuss ANDAs potentially eligible for approval**

OGD Project Management: Initiatives

- Address status of all aspects of ANDA review:**
 - Applications top priority once chemistry acceptable**
 - ANDA PMs serve as spokesperson**
- Prepare action items**
 - attempt to resolve within one week**
 - if ANDA not approved within the week, address at subsequent meeting**

Items to Consider

- **Completeness in Submissions**

- make certain all information provided
- all deficiencies must be addressed in response

- **Clearly identify information on first page of cover letter**

- eg., Minor amendment: chemistry, micro, and labeling deficiencies
- Global submissions

Items to Consider

- **Contact appropriate ANDA PM re: submissions**
 - **Status updates for originals and supplements (except sterility assurance and labeling supplements)**
 - **Notify ANDA PM of any critical information (eg., T.A. ANDA eligible for full approval because won law suit)**
 - **Not certain, contact Rev.Sup. Br. Chief**

Contacts

● ANDA PMs

– Teams 1-4

301-827-5848

– Teams 6-9

301-827-5849

● Bioequivalence PMs

– Teams 1-3

301-827-5847

● Microbiology PM

– Joseph Buccine 301-827-5848